4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Amendment of

Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. This meeting was announced in the <u>Federal Register</u> of June 16, 2016. The amendment is being made to reflect a change in the <u>Procedure</u> portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email:

ODAC@fda.hhs.gov; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the <u>Federal Register</u> of June 16, 2016, 81 FR 39274, FDA announced that a meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee would be held on June 28 and 29, 2016. On page 39274, in the third column, the <u>Procedure</u> portion of the document is changed to read as follows:

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FDA regrets that it was unable to publish this notice 15 days prior to the June 28 and 29,

2016, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee meeting.

Because the Agency believes there is some urgency to bring these issues to public discussion and

qualified members of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory

Committee meeting were available at this time, the Commissioner of Food and Drugs concluded

that it was in the public interest to hold this meeting even if there was not sufficient time for the

customary 15-day public notice.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21

CFR part 14, relating to the advisory committees.

Dated: June 16, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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